



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0832; FRL-9398-1]

Prohydrojasmon; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the biochemical pesticide prohydrojasmon (PDJ) when used as a plant growth regulator in or on apple and grape pre-harvest, in accordance with label directions and good agricultural practices. This regulation eliminates the need to establish a maximum permissible level for residues of PDJ.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0832, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal

holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Gina Burnett, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 605-0513; email address: burnett.gina@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0832 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0832, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of January 9, 2013, (78 FR 1798) (FRL-9374-2), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F8056) by Fine Agrochemicals Ltd. (the petitioner), on behalf of SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192. The petition requested that 40 CFR 180.1299 be amended by establishing an exemption from the requirement of a tolerance for residues of PDJ, propyl-3-oxo-2-pentylcyclopentylacetate, in or on red apples and grapes. The notice referenced a summary of the petition prepared by the petitioner, which is available in the docket, <http://www.regulations.gov>. No substantive comments were received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include

occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider “available information concerning the cumulative effects of [a particular pesticide’s] ... residues and other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

A. Overview of PDJ

PDJ is a synthetically made plant growth regulator that is structurally similar and functionally identical to jasmonic acid (JA), a naturally occurring plant regulator present

in all vascular plants. The jasmonates, of which JA is a member, is a group of plant hormones involved in multiple stages of plant development and defense, including the ability to stimulate fruit ripening. The highest levels of naturally occurring JA are found in actively growing plant tissues such as leaves, flowers, and developing fruit, thus JA has always been a natural component of diets containing plant materials. To date, there have been no reported toxic effects associated with the consumption of JA in fruits and vegetables. See the document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate” (July 16, 2013), available in the docket for this action.

B. Biochemical Pesticide Toxicology Data Requirements

All applicable mammalian toxicology data requirements supporting the petition to exempt residues of PDJ from the requirement of a tolerance in or on apple and grape pre-harvest have been fulfilled. No toxic endpoints were established and no significant toxicological effects were observed in any of the acute toxicity studies. In addition, studies submitted indicate that PDJ is not genotoxic, has no subchronic toxic effects, and is not a developmental toxicant. There are no known effects on endocrine systems via oral, dermal, or inhalation routes of exposure. For a full discussion of the data upon which EPA relied, and its human health risk assessment based on that data, please refer to the document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate” (July 16, 2013). This document, as well as other relevant information, is available in the docket for this action as described under **ADDRESSES**.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

The proposed use patterns may result in dietary exposure to PDJ; however, exposure to residues on treated fruit or foliage is not expected to exist above background levels of naturally occurring JA (see document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate” (July 16, 2013)). No significant exposure via drinking water is expected; PDJ is applied at low rates, rapidly degrades, and is not directly applied to water. Should exposure occur, however, minimal to no risk is expected for the general population, including infants and children, due to the low toxicity of PDJ as demonstrated in the data submitted and evaluated by the Agency, as fully explained in the document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclo-pentylacetate” (July 16, 2013).

B. Other Non-Occupational Exposure

Non-occupational exposure is not expected because PDJ is not approved for residential uses. The active ingredient is applied directly to commodities and degrades rapidly.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or exemption, the Agency consider “available information concerning the cumulative effects of [a particular pesticide’s] ... residues and other substances that have a common mechanism of toxicity.”

EPA has determined PDJ to have a non-toxic mode of action, and the compound does not appear to produce any toxic metabolites. For the purposes of this tolerance action, therefore, the EPA has assumed that PDJ does not have a common mechanism of toxicity with other substances. Following from this, the EPA concludes that there are no cumulative effects associated with PDJ that need to be considered. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

Section 408(b)(2)(C) of FFDCA provides that, in considering the establishment of a tolerance or tolerance exemption for a pesticide chemical residue, EPA shall assess the available information about consumption patterns among infants and children, special susceptibility of infants and children to pesticide chemical residues, and the cumulative effects on infants and children of the residues and other substances with a common mechanism of toxicity. In addition, FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional ten-fold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless EPA determines that a different margin of

safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional or no safety factor when reliable data are available to support a different additional or no safety factor.

As part of its qualitative assessment, EPA evaluated the available toxicity and exposure data on PDJ and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. EPA considers the toxicity database to be complete and has identified no residual uncertainty with regard to prenatal and postnatal toxicity or exposure. No hazard was identified based on the available studies, as fully explained in the document entitled, “Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for Prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclopentylacetate” (July 16, 2013). Based upon its evaluation, EPA concludes that there are no threshold effects of concern to infants, children, or adults when PDJ is applied as a plant growth regulator to stimulate fruit ripening, and used in accordance with label directions and good agricultural practices. As a result, EPA concludes that no additional margin of exposure (safety) is necessary.

VII. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the same reasons that EPA did not apply an extra 10X margin of safety, discussed in Unit VI., and because EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for PDJ.

VIII. Conclusion

EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of PDJ. EPA is therefore establishing an exemption from the requirement of a tolerance for residues of PDJ when used as a plant growth regulator in or on apple and grape pre-harvest, in accordance with label directions and good agricultural practices.

IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this final

rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal

Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 25, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Revise § 180.1299 to read as follows:

§ 180.1299 Prohydrojasmon; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of the biochemical pesticide prohydrojasmon (PDJ), propyl-3-oxo-2-pentylcyclopentylacetate, when used as a plant growth regulator in or on apple and grape pre-harvest, in accordance with label directions and good agricultural practices.